DEEPCHEK®-HIV ASSAYS & SOFTWARE
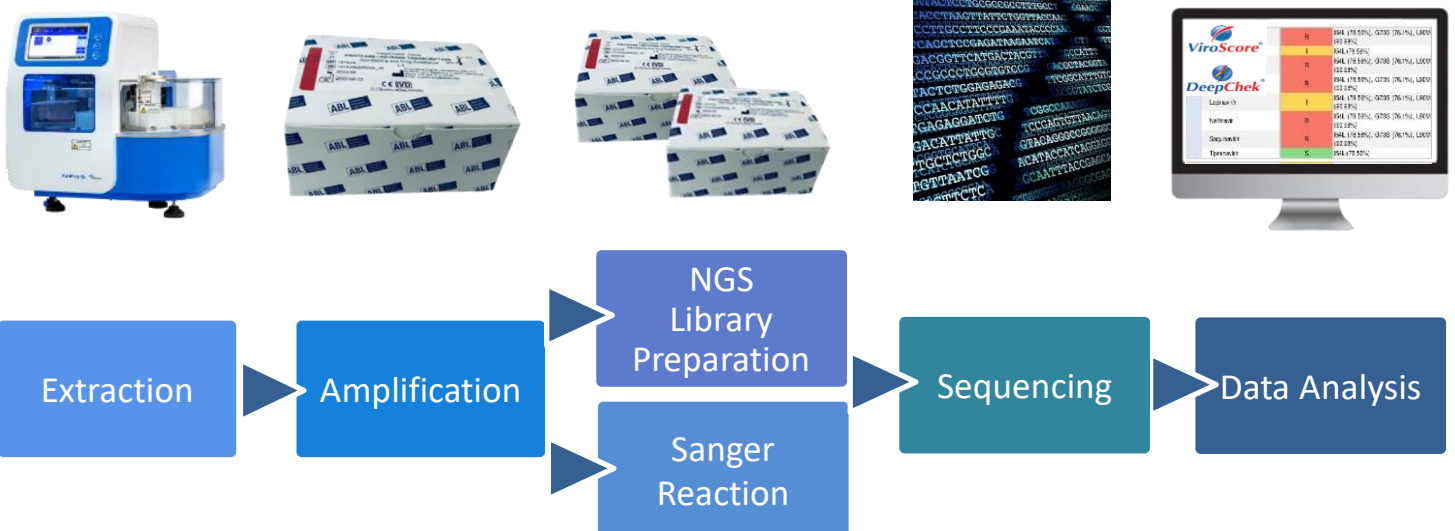
RT/PR – INT – V3 – Whole Genome

A unique and complete portfolio for HIV genotyping through Sanger & Next Generation (NGS) sequencing

These assays are a unique line of products dedicated to HIV-1 Genotyping and resistance determination through Sanger and NGS sequencing.

- RT / PROT (CE-IVD & RUO)
- INT (CE-IVD & RUO)
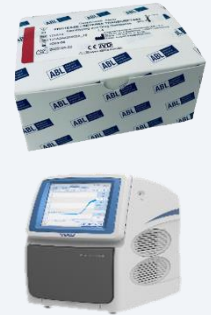- V3 Loop (RUO)
- Whole Genome (CE-IVD & RUO)

Workflow overview

Extraction → Amplification →

NGS Library Preparation

Sanger Reaction

→ Sequencing → Data Analysis

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HIGHLIGHTS

- **PCR AMPLIFICATION** (24 samples/kit)

	SANGER	NGS	
PROT	☑	☑	CE-IVD & RUO
RT	☑	☑	CE-IVD & RUO
INT	☑	☑	CE-IVD & RUO
Whole Genome		☑	CE-IVD & RUO
V3 Loop	☑	☑	RUO

  - **PCR instruments also available through reagent rental**

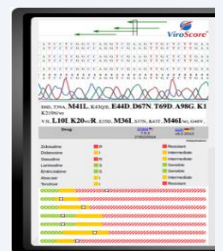- **SEQUENCING**
  - For Sanger & Next Generation Sequencing (NGS)
  - <u>SANGER</u>: DeepChek® SANGER Sequencing Assay
  - <u>NGS</u>: DeepChek® Library Preparation assays (incl. 24/48/96/384 indexes)
  - **Sanger & NGS downstream sequencing instruments also available through reagent rental**

- **DATA ANALYSIS**
  - Downstream sequencing analysis and interpretation with CE-IVD software
  - Genotyping, Tropism determination, Drug resistance interpretation
  - Complete and comprehensive reporting
  - For Sanger (chromatogram editor integrated) & NGS
  - Hosting: On premise (local servers) or Cloud (including Health Data Hosting compliance)
  - **Servers also available through reagent rental**

- **EXTRACTION (KITS & INSTRUMENTS)**
  - Manual or automated
  - Optimized magnetic beads for fast extraction
  - Easy to prepare and very good performance
  - Fast Protocol : 96 samples within 24 minutes
  - **Extraction instrument also available through reagent rental**
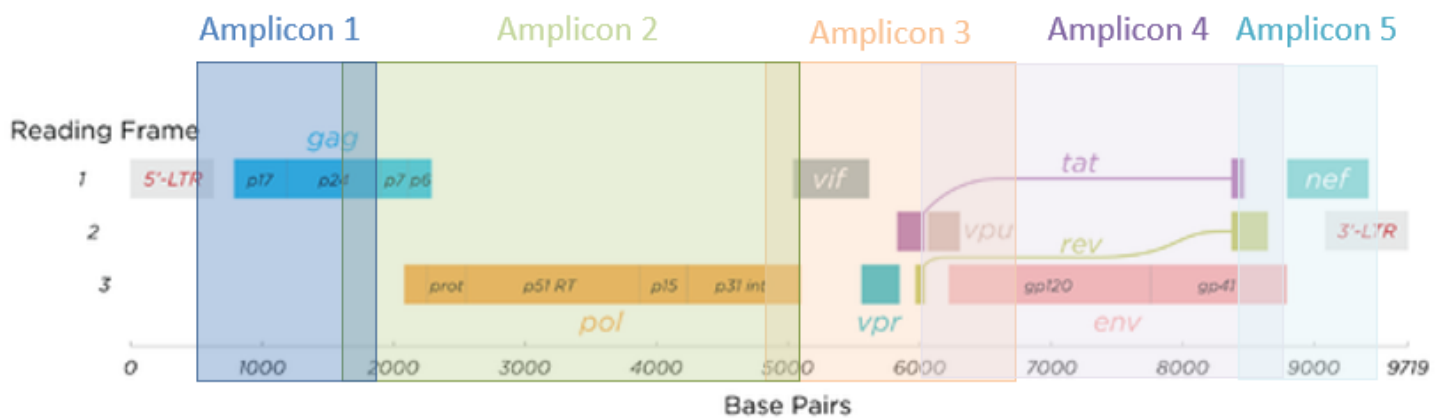

- **AUTOMATION**
  - Pipetting robot – open system to be used for pre- or post-PCR automation
  - IT Services (customization, data import, integration / LIS connectivity …)
  - **Pipetting Robot also available through reagent rental**

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WHOLE GENOME ANALYSIS

DeepChek® Assay Whole Genome HIV-1 Genotyping (24 tests) (CE IVD - 170A24)

- Robust NGS-based kit with Software

- Drug resistance assessment for all classes including new entry & capside inhibitors

- Coverage : 9719 bp

- Number of amplicons: 5x ~750 to 3500 bp

- Sustainable solution for new mutations / drugs / classes

- Amplicons can be pooled with other DeepChek® applications (Ex. HCV, SARS-CoV-2)

- Can be used for runs of 24 / 48 / 96 / 384 samples

- 3-4 days for full workflow

- Push-button analysis

- Compatible with most NGS platforms

Drug Resistance Assessment for new antiretroviral drugs (entry & capside inhibitors)

	Generic name	Assessment	Resistance mutations >20.00%
PI	Atazanavir/r	I	A71V (99.2%), L90M (97.22%)
	Darunavir/r 600/100 mg BID	S	
	Darunavir/r 800/100 mg QD	S	
	Lopinavir/r	I	L10R (99.07%), A71V (99.2%), L90M (97.22%)
	Tipranavir/r	S	
NRTI	Abacavir	I	M41L (98.73%), T215Y (86.18%)
	Emtricitabine	S	
	Islatravir	S	
	Lamivudine	S	
	Tenofovir	I	M41L (98.73%), T69D (98.67%), T215Y (86.18%)
	Zidovudine	R	T215Y (86.18%)
NNRTI	Doravirine	S	
	Efavirenz	R	Y181C (86.49%)
	Etravirine	R	Y181C (86.49%)
	Nevirapine	R	Y181C (86.49%)
	Rilpivirine	R	Y181C (86.49%)
INI	Bictegravir	S	
	Cabotegravir	S	
	Dolutegravir 50mg BID	S	
	Dolutegravir 50mg QD	S	
	Elvitegravir	S	
	Raltegravir	S	
EI	Enfuvirtide	S	
	Fostemsavir	S	
CI	Lenacapavir	S	

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HIGHLIGHTS on the DeepChek® technology

ROBUST
CE-IVD and RUO

FLEXIBLE
For low to high throughput (1-384 samples in one run)

FAST
~1-2 days (SANGER)
~2-4 days (NGS)

STANDARDIZED
Kits, Software, Support, Integration with LIMS/HIS, Automation
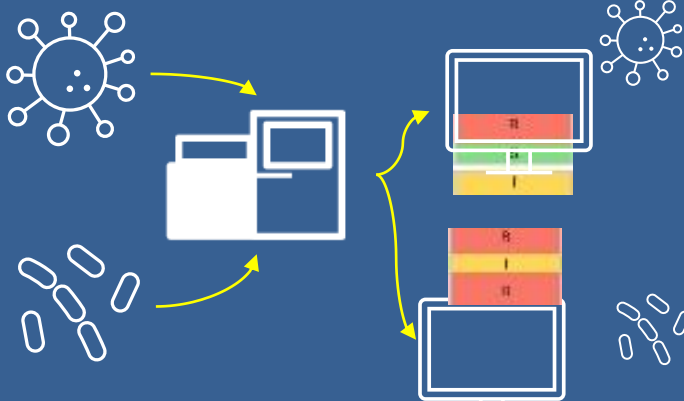
COMPREHENSIVE
Genotyping, Drug Resistance, Tropism, Reporting, Storage…

SECURED
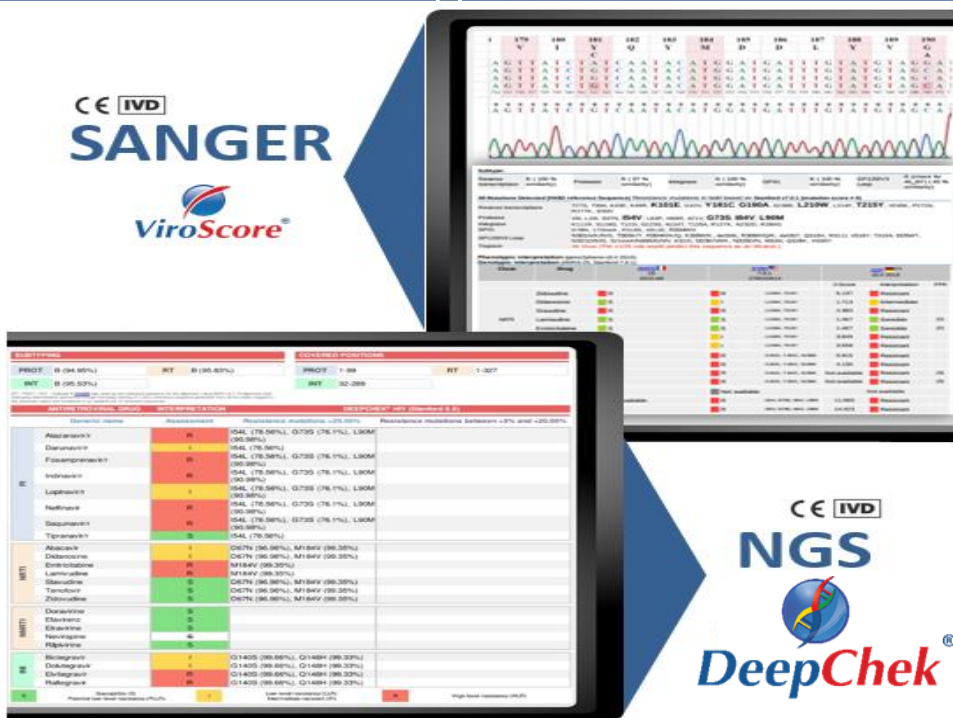Healthcare Cloud Access, Local installation

POOLING CAPACITY

Pool several DeepChek® Libraries (samples) from different applications in the same NGS run
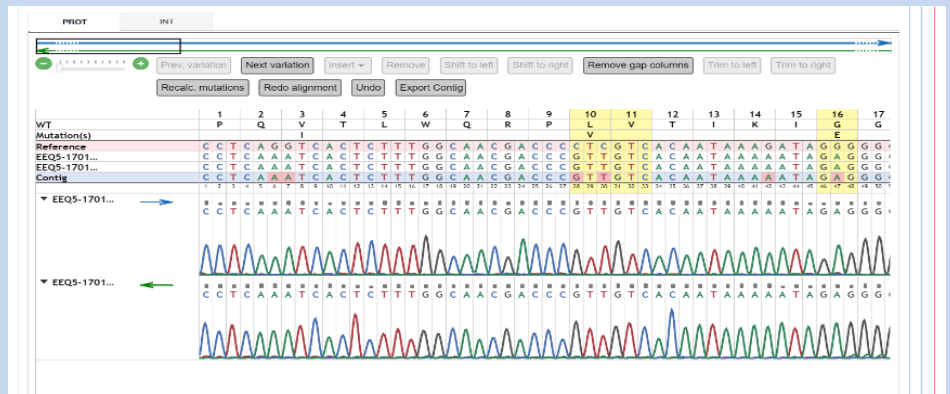
COST EFFECTIVE

- HIV
- SC2
- TB
- HCV
- HBV
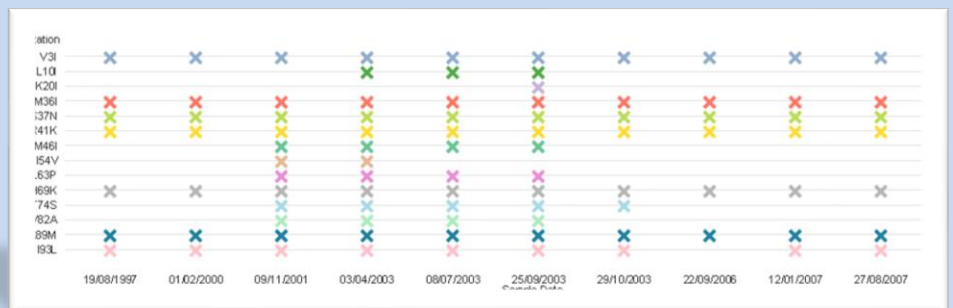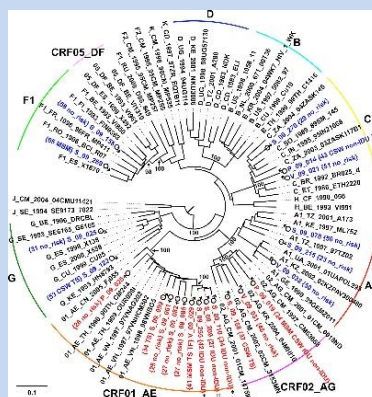- CMV
- HSV
- 16s
- RNA
- HPV
- BKV
- …

REPORTING

CE IVD
SANGER
ViroScore®

CE IVD
NGS
DeepChek®

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KEY FEATURES

EMBEDDED CHROMATOGRAM EDITOR

SINGLE or CUMULATIVE GENOTYPING

SUBTYPING DRUG RESISTANCE ASSESSMENT

- HIVDB/STANFORD
- ANRS
- REGA
- GENO2PHENO
- HIV-GRADE
- RIS
- RENAGENO

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OTHER FEATURES

Technology
- Web-based (browser only)
- Software & database
- Local or Cloud (+HDS) hosting
- Unlimited user accounts
- Unlimited analyses

Security
- Data access restriction (pools, read-only mode…)
- Logging of user accesses
- Encrypted database
- Reports validation

Additional features
- Report customization
- Contamination check
- Quality control
- Export (reports, FASTA, XML…)
- Batch mode analysis
- Data mining

Main features
- SANGER data management (AB1, FASTA) with embedded chromatogram editor
- NGS data management (FASTQ) with dedicated pipeline
- Genotyping (per sample & cumulative)
- Subtyping
- Virtual-phenotyping
- Drug resistance through up-to-date guidelines
- GSS determination and regiment ranking
- Tropism
- Reporting & labelling

Services
- Constant updates
- Annual upgrades (versions)
- Historical data import
- LIMS integration
- HIS integration
- Support
- Trainings

REFERENCES & CONTACT

Product:	Reference:
DeepChek® CE-IVD Assays	
PR / RT Genotyping and Drug Resistance (CE-IVD)	121A24
INT Genotyping and Drug Resistance (CE-IVD)	122A24
DeepChek® Assay Whole Genome HIV-1 Genotyping (CE-IVD)	170A24
PR / RT Sequencing V1 (CE-IVD) (accessory for 121A24) (Sanger)	125A24
INT Sequencing V1 (CE-IVD) (accessory for 122A24) (Sanger)	126A24
DeepChek® RUO Assays	
PR / RT Genotyping and Drug Resistance (RUO)	101B24
INT Genotyping and Drug Resistance (RUO)	102C24
V3 Loop/Tropism Assay (RUO)	103A24
General Laboratory Products	
DeepChek® SANGER SEQUENCING REACTION V2 (24rx/48rx)	123A24/123A48
DeepChek® NGS LIBRARY PREPARATION V1 (24 indexes)	116B24+124B24
DeepChek® NGS LIBRARY PREPARATION V1 (48 indexes)	116B48+124B48
DeepChek® NGS LIBRARY PREPARATION V1 (96 indexes)	116B96+124B96
DeepChek® NGS LIBRARY PREPARATION V1 (384 indexes)	116B384+124B384
DeepChek® NGS Clean-up beads (60mL)	N411-02
DeepChek® 96x0.2 mL wells plate (25 units)	B70501-01
Software – HIV module	
DeepChek® (CE-IVD)	S-12-023 (HUS)
ViroScore® (CE-IVD)	S-09-014 (VSH)

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